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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,386	ZHU ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/2/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-42 are pending.

2. Applicant's election with traverse of Group V, claim 36 in the reply filed on 6/1/2006 is acknowledged.

The traversal is on the ground(s) relating to the Office's characterization of Groups IV and VI are related as process of making and product made. Applicants contend there is no evidence that the claimed product can be isolated from their source organism and that the Office has not shown how this is materially different from the claimed process (page 2 or Response, 1st full paragraph).

This is not found persuasive because the Office contends isolating proteins is known in the art. This is especially true for isolating proteins from plants. The Office contends that prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide.

In regards to Groups I and VI and inventions II and III and in regards to Groups I and IV, product and process of use, Applicants contend the Office has failed to show that the proposed uses are materially different from the claimed use (page 2 of Response, 2nd full paragraph and paragraph bridging pages 2 and 3 of Response).

This is not found persuasive because the Office contends that the nucleic acids of Group I can be used in different method steps such as nucleic acid hybridization and as such are distinct inventions according to MPEP §806.05(h) and the same is true for the proteins of Group VI.

In regards to Groups I and VI and Group V, product and process of use, Applicants contend the Office has not provided reasons and/or examples that the method of Group V can use

a nucleic acid molecule encoding an enhancer of SOS1 expression (page 3 of Response, 1st full paragraph).

This is not found persuasive because the Office contends that one skilled in the art recognizes the value of doing an enhancer/suppressor screen of a designated gene. The results of such a screen would include nucleic acid molecules that can be used to enhance the expression of the designated gene. Such methods are known in the art (See for example, Onouchi et al., 2000, The Plant Cell 12(6):885-900) and therefore, the inventions of Groups I, V and VI are distinct as specified in MPEP §806.05(h).

In regards to the inventions of Groups II-V, that the groups are unrelated due to divergent method steps, Applicants contend the Office has not provided sufficient reasons and/or examples to support this assertion (page 3 of Response, 2nd paragraph).

This is not found persuasive because the Office contends one skilled in the art recognizes that the methods involved in each of the different inventions of Groups II-V are distinct from each other. For example, the expression system for making a protein requires an expression system comprising a nucleic acid subcloned into an expression construct which has been transformed into bacteria versus PCR reactions that do not use expression constructs, but rather use primers and a polymerase and the use of a PCR machine.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-35 and 36-42 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claim 36 is examined in the present office action.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example pages 5 and 6. See MPEP § 608.01.

Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. In the instant application, see pages 13 and 14 and Figures 3A, 4A, and 7A-7D.

On page 17, last line, SOS1 is misspelled.

On pages 19, last paragraph, 2nd line, and second to last line and page 20, 1st line, there is a typographical error comprising the letter "W".

The Specification is objected to because the drawings are not referred to properly. If the drawings show Figures 1A and 1B, then the Brief Description of the Drawings should recite "Figures 1A-1B", instead of "Figure 1". Correction is requested.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a method of increasing the salt tolerance of a plant comprising enhancing the expression of the SOS1 gene in said plant.

Applicants' invention is SEQ ID NO:1 (*SOS1*) encoding a Na^+/H^+ antiporter. Mutations in *SOS1* cause a salt-hypersensitive phenotype (page 15, 1st paragraph of "Results" section). *SOS1* was positionally cloned from *Arabidopsis* and is expressed constitutively through-out the plant but is upregulated in response to NaCl treatment. The Arabidopsis genomic sequence of SOS1 is disclosed in Figures 7A-7D and corresponds to SEQ ID NO:1 and the encoded protein is disclosed in Figure 3A and corresponds to SEQ ID NO:2.

Applicants do not disclose a representative number of SOS1 nucleic acid sequences from a representative number of plants encoding a SOS1 polypeptide. In addition, Applicants do not identify the essential regions of the SOS1 protein from all plants.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly

and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences from plants encoding a SOS1 protein falling within the scope of the claimed genus of all SOS1 genes from all plants. Applicants only disclose SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the SOS1 protein, it remains unclear what features identify an Arabidopsis SOS1 protein. Since the genus of SOS1 proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

6. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *In re Wands* factors (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claim is drawn to a method of increasing the salt tolerance of a plant comprising enhancing the expression of the SOS1 gene in said plant.

Applicants define "enhancement" to mean increasing the intracellular activity of one or more enzymes in a plant cell and/or plant which are encoded by the corresponding DNA (page 8 of specification, 3rd paragraph). Applicants state "Enhancement can be achieved with the aid of various manipulations of the bacterial cell" (*Ibid*). Applicants also disclose that enhancement particularly over-expression, the number of copies of the corresponding gene can be increased, or a strong promoter can be used or the promoter and regulation region or ribosome binding site can be mutated (*Ibid*). The Office also interprets enhancement to encompass genetic manipulations which affect enhancers and/or suppressors of SOS1 expression.

Applicants' invention is SEQ ID NO:1 (*SOS1*) encoding a Na^+/H^+ antiporter. Mutations in *SOS1* cause a salt-hypersensitive phenotype (page 15, 1st paragraph of "Results" section). *SOS1* was positionally cloned from *Arabidopsis* and is expressed constitutively through-out the plant but is upregulated in response to NaCl treatment. *SOS1* mRNA is more abundant in roots than in shoots (page 17, 2nd paragraph). The Arabidopsis genomic sequence of SOS1 is disclosed in Figures 7A-7D and corresponds to SEQ ID NO:1 and the encoded protein is disclosed in Figure 3A and corresponds to SEQ ID NO:2.

Applicants have not taught how one skilled in the art would make a plant with increased salt tolerance comprising enhancing the expression of the SOS1 gene in the plant. Applicants have not disclosed how manipulating a bacterial cell will enhance the expression of the SOS1 gene in a plant. In addition, Applicants have not disclosed any mutagenesis screens in which the promoter or regulation region or ribosome binding sites have been mutated which results in enhanced expression of any SOS1 gene. Applicants teach that *Arabidopsis* plants comprising a mutant *sos2* gene are less tolerant of high Na^+ environments or Na^+ / K^+ imbalances but Applicants have not taught enhancing the expression of any SOS1 gene to produce a plant with increased salt tolerance.

Applicants have not reduced to practice their invention. Applicants have only used the *SOS1* nucleic acid to complement a *sos1* mutant, and one skilled in the art would not have a need to make a wild-type plant from a *sos1* mutant. Applicants disclose a method for increasing the salt tolerance of a plant comprising transforming a plant with the Applicants' invention (page 5, 1st full paragraph) but Applicants have not provided further guidance as to the spatial and temporal expression that is required to achieve the desired result. Applicants disclose that their

invention is a Na^+/H^+ antiporter. Shi et al (2000, PNAS 97(12):6896-6901) teach that anitporters require a proton motive force to be operable (page 6896, 2nd paragraph). Applicants have not taught whether the endogenous H^+ -ATPases would be sufficient to establish the proper H^+ gradient that would be required by the increased number of Na^+/H^+ antiporters that would comprise a plant transformed with Applicants' invention.

Larkin et al (1994, The Plant Cell 6:1065-1076) teach the unpredictability of transforming a plant to produce the opposite phenotype as the mutant-gene phenotype. Larkin et al teach that *GLABROUS1* (*GL1*) mutant plants have a reduced number of trichomes. Over-expressing GL1 in *Arabidopsis* does not produce plants with an increased number of trichomes compared to wild-type plants (page 1072, right column, 1st paragraph). Therefore, just because the *sos1* mutants exhibit an increased sensitivity to high Na^+ concentrations, does not mean that over-expressing *SOS1* will automatically produce plants with an increased tolerance to Na^+.

Applicants have also not disclosed a method of enhancing SOS1 expression comprising manipulation of the bacterial cell, or mutating the ribosomal binding site or mutating the regulation region of the promoter. Applicants have not disclosed any methods to mutate plant genes and select for genes that enhance the expression of any SOS1 in a plant.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through bacterial manipulation to produce enhancement

of SOS1 expression, or to mutate non-disclosed regulatory regions of any SOS1 gene or to mutate non-disclosed regions of ribosomal binding sites or to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SOS1 gene of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SOS1 protein of SEQ ID NO:2, and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed enhance the expression of any SOS1 gene of any plant and produce a plant that has increased salt tolerance.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
June 21, 2006

STUART F. BAUM, PH.D.
PATENT EXAMINER